K003102

INNOVATIVE
MEDICAL
DEVICES

PARÉ SURGICAL, INC.
7332 S. Alton Way, Unit H
Englewood, CO 80112

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PARÉ

FEB 2 7 2001

510(k) Summary

As required under Section 513(i)(3)(A) of the Safe Medical Device Act of 1990, an adequate summery of any information respecting the safety and effectiveness follows:

A. General Information:

Name and address of submitter:	PARÈ Surgical, Inc. 7332 S. Alton Way, Suite H Englewood, CO 80112
Contact:	Richard Fleenor President Phone: 303.689.0187 Fax: 303.689.0579
Date of summery:	December 27, 2000
Name of device:	PARÈ Endoscopic Suturing System
Common name:	Endoscopic Suturing Device
Classification:	78KOG- Endoscopic Suturing Device

B. Predicate Devices:

Company	Trade Name	510(k) Number
1. PARÈ Surgical, Inc.	Quik-Stitch™ Endoscopic Suturing System	K953123
2. BARD	Bard Endoscipic Suturing System	K994290

C. Description:

The PARÉ Endoscopic Suturing System consists of three concentric tubes and a wire that can fit down the operating channel of a flexible endoscope. Each of the concentric tubes controls a function that is required to do soft tissue suturing at the distal end of the endoscope. These functions include:

1. A needle, which is used to puncture through the soft tissue
2. A loop, which is used to capture the free end of the suture.
3. A holder for the suture that is formed into a pre-tied knot.
4. A knot pusher, which also performs the function of cutting the suture once the knot is positioned and formed.

The device will be loaded only with sutures that have received FDA approval for human use.

D. Intended Use:

The PARÉ Endoscopic Suturing System will allow the surgical physician to suture soft tissue when doing gastroenterological procedures using the operating channel of a flexible endoscope.

E. Technological Characteristics Summary:

The technological characteristics of the PARÉ Endoscopic Suturing System is the same or similar to the predicate devices in that the materials used to manufacture these products are the same type of medical grade stainless steels and plastics. The products all share common features such as material types provide a means for driving a needle through soft tissue and capturing the suture in the distal side. They all suture soft tissue by manually actuating the needle with a handle mechanism. They all are designed to allow reloading of suture to deliver multiple stitches under endoscopic visualization. Further, the PARÉ Endoscopic Suturing System and the predicated devices have the same of similar intended use, that is too place stitches and tie suture material to approximate soft tissue under endoscopic visualization.

F. Performance Data:

Bench test results using fresh swine esophagus, stomach and colon soft tissue showed that the materials chosen to be utilized in the PARÈ Endoscopic Suturing System meet the established specifications necessary for consistent performance of its intended use. The device was invitro tested six times using the operating channel of an Olympus Colonoscope type CF-1T140 and six times using an Olympus Gastroscope type GIF-PQ20. In all experiments the device was able suture the soft tissue including the dropping of the pre-tied knot.

510(k) Number : K003102

Device Name: PARÈ Endoscopic Suturing System

Indication For Use: The PARÈ Endoscopic Suturing System will allow the surgical physician to suture soft tissue when doing gastroenterological procedures using the operating channel of a flexible endoscope.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X___ OR Over -The Counter Use____ (Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Mr. Richard P. Fleenor
President
Pare Surgical, Inc.
7332 S. Alton Way, Unit H
Englewood, Colorado 80112

Re: K003102
Trade Name: PARE Endoscopic Suturing System
Regulatory Class: II
Product Code: KOG
Dated: December 27, 2000
Received: December 28, 2000

Dear Mr. Fleenor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number : K003102

Device Name: PARÈ Endoscopic Suturing System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X___ OR Over -The Counter Use____ (Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003102